IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No.: ISPH-0764

Inventors: Bennett and Wyatt

Serial No.: Not yet assigned

Filing Date: Herewith

Examiner: Not yet assigned

Group Art Unit: Not yet assigned

Title: Antisense Modulation of Phospholipase

A2, Group IIA (Synovial) Expression

"Express Mail" Label No. **EL976562840US** Date of Deposit <u>August 18, 2003</u>

I hereby certify that this paper is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to the Commissioner for Patents, Mail Stop Sequence, P. O. Box 1450, Alexandria, VA 22313-1450.

By <u>Jane Massey Licata, Reg. No. 32,257</u>

Commissioner for Patents Mail Stop Sequence P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).

- (XX) In accordance with §1.97(b), since this Information

 Disclosure Statement is being filed either within three months of the filing date of the above-identified application, within three months of the date of entry into the national stage of the above identified application as set forth in §1.491, or before the mailing date of a first Office Action on the merits of the above-identified application, no additional fee is required.
- () In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, therefore:
 - () Certification in Accordance with §1.97(e) is attached hereto; or
 - () The fee of \$180.00 as set forth in \$1.17(p) is attached.
- () In accordance with §1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311 but before the payment of the Issue Fee, therefore included are: Certification in Accordance with §1.97(e); Petition Requesting Consideration of the Information Disclosure Statement; and the fee of \$130.00 as set forth in §1.17(I)(1).
- () Copies of each of the references listed on the attached Form PTO-1449 (modified) are enclosed herewith.

(XX) In accordance with §1.98(d), copies of some or all of the references listed on the attached Form PTO-1449 (modified) are not enclosed herewith because they were previously submitted to the U.S. Patent and Trademark Office in prior application Serial No. 09/865,866, filed May 25, 2001, for which a claim for priority under 35 U.S.C. §120 has been made in the instant application.

Please charge any deficiency or credit any overpayment to Deposit Account No. 50-1619. This form is submitted in duplicate.

- () The relevance of the listed references in a foreign language is as stated in the specification at pages @@.
- (XX) All listed references are in the English language.

Respectfully submitted,

Jankery Lectr.

Jane Massey Licata Registration No. 32,257

Date: August 18, 2003

Licata & Tyrrell P.C. 66 E. Main Street Marlton, New Jersey 08053

(856) 810-1515

Form PTO-1449 Modified			Docket No. ISPH-0764	Serial No. not yet assigned	
List of Patents and Publications Cited by Application (Use several sheets if necessary)			Applicant C. Frank Bennett <i>et al</i> .		
U.S. Department of Commerce Patent and Trademark Office			Filing Date herewith	Group	
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)					
	AA	Abe et al., Group I peritoneal and pleu various types of ca 250.	ıral ettusions in į	patients with	
	AB	Barbour et al., Antisense inhibition of group II phospholipase A2 expression blocks the production of prostaglandin E2 by P388D1 cells, J. Biol. Chem., 1993, 268:21875-21882.			
	AC	Bennett et al., Sequence specific inhibition of human type II phospholipase A2 enzyme activity by phosphorothicate oligonucleotides, Nucleic Acid Res., 1994, 22, 3202-3209.			
	AD	Bidgood et al., Type IIA secretory phospholipase A2 upregulates cyclooxygenase-2 and amplifies cytokinemediated prostaglandin production in human rheumatoid synoviocytes, J. Immunol., 2000, 165:2790-2797.			
	AE	Bryant et al., 1,3-Dioxane-4,6-dione-5-carboxamide-based inhibitors of human group IIA phospholipase A: X-ray structure of the complex and interfacial selection of inhibitors from a structural library, Bioorg. Med. Chem. Lett., 1999, 9:1097-1102.			
	AF	Chilton et al., Antigen-induced generation of lyso- phospholipids in human airways, J. Exp. Med., 1996, 183:2235-2245.			
	AG	expression of a nov	upillard et al., Cloning, chromosomal mapping, and expression of a novel human secretory phospholipase A2, Biol. Chem., 1997, 272:15745-15752.		
	AH	Dennis, Diversity of group types, regulation, and function of phospholipase A2, J. Biol. Chem., 1994, 269:13057-13060.			
	AI	Dennis, The growing phospholipase A2 superfamily of signal transduction enzymes, Trends Biochem. Sci., 1997, 22:1-2.			
	AJ	Dorsam et al., Diphenyleneiodium chloride blocks inflammatory cytokine-induced up-regulation of group IIA phospholipase A(2) in rat mesangial cells, J. Pharmacol. Exp. Ther., 2000, 292:271-279.			
EXAMINER		111111111111111111111111111111111111111	DATE CONSIDERED		

Form PTO-1449 Modified Serial No. . Docket No. not-yet assigned ISPH-0764 List of Patents and Publications Applicant Cited by Application C. Frank Bennett et al. (Use several sheets if necessary) Filing Date Group U.S. Department of Commerce Patent herewith and Trademark Office OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) ΑK Furue et al., Crucial role of group IIA phospholipase A(2) in oleic acid-induced acute lung injury in rabbits, Am. J. Respir. Crit. Care Med., 1999, 160:1292-1302. Ivandic et al., Role of group II secretory ALphospholipase A2 in atherosclerosis: 1. Increased atherogenesis and altered lipoproteins in transgenic mice expressing group IIa phospholipase A2, Arterioscler. Thromb. Vasc. Biol., 1999, 19:1284-1290. Jamal et al., Increased expression of human type IIa MA secretory phospholipase A2 antigen in arthritic synovium, Ann. Rheum. Dis., 1998, 57:550-558. Kano et al., Effects of long-term ursodeoxycholate ANadministration on expression levels of secretory lowmolecular-weight phospholipases A2 and mucin genes in gallbladders and biliary composition in patients with multiple cholesterol stones, Hepatology, 1998, 28:302-313. Group IIA phospholipase A2 mediates lung ΑO Koike *et al.,* injury in intstinal ischemia-reperfusion, Ann. Surg., 2000, 232:90-97. Koyama et al., Elevations of group II phospholipase A2 concentrations in serum and amniotic fluid in association with preterm labor, Am.J. Obstet. Gynecol., 2000, 183:1537-1543. Kudo et al., Mammalian non-pancreatic phospholipases ΑQ A2, Biochim. Biophys. Acta, 1993, 1170:217-231. Lilja et al., Presence of group IIa secretory AR phospholipase A2 in mast cells and macrophages in normal human ileal submucosa and in Crohn's disease, Clin. Chem. Lab Med., 2000, 38:1231-1236. Lin et al., Secretory phospholipase A2 as an index of AS disease activity in rheumatoid arthritis. Prospective double blind study of 212 patients, J. Rheumatol., **1996**, *23*:1162-1166. Minami et al., Elevation of phospholipase A2 protein in AT sera of patients with Crohn's disease and ulcerative colitis, Am. J. Gastroenterol., 1993, 88:1076-1080.

DATE CONSIDERED

EXAMINER

4,000,00

Serial No. , Docket No. Form PTO-1449 Modified not yet assigned ISPH-0764 List of Patents and Publications Applicant C. Frank Bennett et al. Cited by Application (Use several sheets if necessary) Filing Date Group U.S. Department of Commerce Patent herewith and Trademark Office OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) Increased group II phospholipase A2 in Minami et al., ΑU colonic mucosa of patients with Crohn's disease and ulcerative colitis, Gut, 1994, 35:1593-1598. Nevalainen, Serum phospholipases A2 in inflammatory VΑ diseases, Clin. Chem., 1993, 39:2453-2459. Pruzanski et al., Circulating group II phospholipase AW A2 activity and antilipocortin antibodies in systemic lupus erythematosus. Correlative study with disease activity, J. Rheumatol., 1994, 21:252-257. Pruzanski et al., Lipoproteins are substrates for ΑX human secretory group IIA phospholipase A2: preferential hydrolysis of acute phase HDL, J. Lipid Res., 1998, 39:2150-2160. Shoda et al., Secretory low-molecular-weight phospholipases A2 and their specific receptor in bile ducts of patients with intrahepatic calculi: factors of chronic proliferative cholangitis, Hepatology, 1999, 29:1026-1036. Snyder et al., Pharmacology of LY315920/S-5920, [[3-(aminooxoacetyl)-2-ethyl-1-(phenylmethyl)-1H-indol-4-A 7. yl]oxy] acetate, a potent and selective secretory phospholipase A2 inhibitor: A new class of anti-inflammatory drugs, SPI, J. Pharmacol. Exp. Ther., 1999, 288:1117-1124. Vadas et al., Extracellular phospholipase A2 expression and inflammation: the relationship with associated disease states, J. Lipid Mediat., 1993, 8:1-Wada et al., Systemic autoimmune nephritogenic BB components induce CSF-1 and TNF-alpha in MRL kidneys, Kidney Int., 1997, 52:934-941. Weinrauch et al., Mobilization of potent plasma BC bactericidal activity during systemic bacterial challenge. Role of group IIA phospholipase A2, J. Clin. Invest., 1998, 102:633-638.

DATE CONSIDERED

EXAMINER

 $v_{0,0}\geqslant y$

	• .	·			
Form PTO-1449 Modified	Docket No. ISPH-0764	Serial No. not yet assigned			
List of Patents and Publications Cited by Application (Use several sheets if necessary)	Applicant C. Frank Bennett et al.				
U.S. Department of Commerce Patent and Trademark Office	Filing Date herewith	Group			
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)					
BD Yokota et al., Suppression of murine endotoxic shock by sPLA2 inhibitor, indoxam, through group IIA sPLA2-independent mechanisms, Biochim. Biophys. Acta, 1999, 1438:213-222.					
EXAMINER	DATE CONSIDERED				

ingiale.

social speed

Form PTO-1449 Modified Docket No. TSPH-0764 Applicant List of Patents and Publications Cited by Application C. Frank Bennett et al. (Use several sheets if necessary) U.S. Department of Commerce Filing Date Group Patent and Trademark Office U.S. PATENT DOCUMENTS Class Subclass Examiner's Document No. Date Name Initial AA 5,019,508 5/28/1991 Johnson et al. 434 198 AΒ AC ADΑE AF AG AH ΑI ΑJ AK ALAMFOREIGN PATENT DOCUMENTS Translation Country Examiner's Document No. Date YES NO Initial ÃΟ WO 91/16901 11/14/1991 PCT AP .. __ ΑQ AR AS AT AU ΑV ΑW AXDATE CONSIDERED EXAMINER

Docket No. Serial No. Form PTO-1449 Modified ISPH-0764 Not yet assigned List of Patents and Publications Applicant Cited by Applicant Bennett and Wyatt (Use several sheets if necessary) Filing Date Group U.S. Department of Commerce Herewith Not yet assigned OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) Milner et al., "Selecting effective antisense reagents ΒA on combinatorial oligonucleotide arrays", Nature Biotechnology 1997 15:537-541 EXAMINER DATE CONSIDERED

Docket No. Serial No. . Form PTO-1449 Modified ISPH-0764 Not yet assigned List of Patents and Publications Applicant Cited by Applicant (Use several sheets if necessary) Bennett and Wyatt Filing Date Group U.S. Department of Commerce Patent and Trademark Office Herewith Not yet assigned U. S. PATENT DOCUMENTS Examiner Document Date Name Class Subclass McKay et al. CA 5,877,309 3-2-99 536 24.5 FOREIGN PATENT DOCUMENTS Examiner Document No. Date Translation Country NO YES Initial EXAMINER DATE CONSIDERED